

amendment to Claim 12 serves to correct the dependency of Claims 12-16 in view of the cancellation of Claim 11 and the addition of Claim 23. Claim 23 is the same as Claim 11 which was directed to monitoring fluorescence during PCR, except that the new claim recites quantitation, rather than monitoring, as its object, and has the additional step of quantitation based on monitoring. Therefore, Claim 23 is patentable for the same reason that Claim 11 is patentable.

Claim 23 is directed to methods for quantitation of a target nucleic acid in a sample. The additional claims are fully supported by the specification as originally filed. For example, Applicant directs attention to the specification, particularly at page 19, line 33, through page 20, line 7; page 24, beginning at line 21, Example IV, entitled "Quantitative Measurement of Target Specific Ethidium Bromide Fluorescence;" and page 28 beginning with line 24, at Example VII, entitled "A Method For Automated/On-Line Detection of PCR Product During Amplification." These sections of Applicant's application teach and exemplify the terms of the proposed claim as follows:

1. Amplifying a target nucleic acid in the presence of a fluorescent pigment whose fluorescence intensity is increased upon intercalation into a double-stranded nucleic acid;

See the specification at any of Examples I through VII where a target nucleic acid is amplified by a polymerase chain reaction in the presence of ethidium bromide.

2. monitoring the fluorescence intensity of said fluorescent pigment during said polymerase chain reaction; and

See the specification at Example VII which sets forth "a method for quantitative detection of PCR product" by means of a device for monitoring amplification during a polymerase chain reaction. The resulting data are presented at figures 5A and 5B. The specification describes an apparatus for monitoring fluorescence in order to achieve quantification during PCR at page 14, line 1, through, page 15, line 13.

3. determining the quantity of said target nucleic acid in said sample.

PATENT  
Atty. Docket No. 2599

See the specification at page 19, line 33, through page 20, line 7 and page 18, lines 31-37, where various means for determining the amount of target nucleic acid present in the sample are described.

The amendment to Claim 12 and the additional claim do not add new matter, and the Higuchi party requests that the amendments be entered.

The Commissioner is hereby authorized to charge any fees in connection with this amendment to Deposit Account No. 08-2525.

Respectfully submitted,

By:

  
Stacey R. Sias, Ph.D.  
Agent for Applicant  
Reg. No. 32,630

March 2, 1995

Hoffmann-La Roche Inc.  
340 Kingsland Street  
Nutley, NJ 07110-1199  
In California (510) 814-2863

PATENT  
Atty. Docket No. 2599

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of March, 1995, a copy of the foregoing document was served on the party Mitoma in Interference No. 103,489 by mailing the same, via Federal Express addressed to their attorney of record, whose address of record is

Steven B. Kelber  
Oblon, Spivak, McClelland  
Maier and Neustadt  
Fourth Floor  
1755 Jefferson Davis Highway  
Arlington, Virginia 22202

Respectfully submitted,



\_\_\_\_\_  
Stacey R. Sias, Ph.D.  
Reg. No. 32,630